REMARKS/ARGUMENTS

This letter is responsive to the Office Action dated **July 9, 2003**. Under separate sheet of cover, applicant encloses a request for a three-month extension of time. By this amendment, the abstract, specification, drawings and claims are amended. No new subject matter is added. Reconsideration in view of the above amendments and following remarks is respectfully requested.

Amendments to the Abstract

Applicant submits that the amendments made to the abstract were made to clarify the description of the invention, and do not add new subject matter to the application.

Amendments to the Specification

Applicant submits that the amendments made to the specification were made to correct typographical errors, and do not add new subject matter to the application.

Amendments to the Claims

Applicant submits that the amendments made to Claims 1, 4, 6, 8 and 9 were made to clarify the invention and correct typographical errors, and do not add new subject matter to the application.

Amendments to the Drawings

Applicant submits herewith 4 replacement sheets of formal drawings to replace the originally filed drawings that are presently on file.

Rejections under 35 USC 103

Applicant confirms that the subject matter of the claims was commonly owned at the times any inventions covered therein were made.

The Examiner rejects Claims 1-6, 8, 9, and 12 under 35 USC 103(a) as being unpatentable over Brenneman (US Patent No. 5,466,220) in view of Haber et al. (US Patent No. 5,562,616), Morell (US Patent No. 5,389,070), Lynn et al. (US Patent No. 5,549,569), and Nowakowski (US Patent No.6,159,232). The Examiner acknowledges that Brenneman does not disclose a 3-way valve connected to a tubulation. However, the Examiner argues that it is well known to connect tubulations, vials, syringes and IV bags to 3-way valves in order to transfer medication or mix medications or other fluids. Reconsideration is requested in light of the following arguments.

Brenneman (US Patent No. 5,466,220) teaches a drug vial mixing and transfer device that has a unique structure and operates in a different way from the pharmaceutical delivery system as claimed in the present invention. Brenneman teaches a transfer device having a valve 12 with a first fluid passageway 23, a second fluid passageway 21, and a third fluid passageway 25. A first housing 42 communicates with the open end of the first fluid passageway 23 of the valve 12 for receiving a first vial 52 containing a liquid diluent. A second housing 32 communicates with the open end of the second fluid passageway 21 for receiving a second vial 50 containing a powdered drug. A third fluid passageway 25 is connected directly to a syringe 60. In operation, the valve 12 is turned to position "1" so that the first fluid passageway 23 and the third fluid passageway 25 are in fluid communication. The liquid diluent from the vial 52 is drawn into the syringe 60 by withdrawing a plunger 62 within the syringe. The valve is then turned to position "2" so that the second fluid passageway 21 and the third fluid passageway 25 are in fluid communication. The plunger 62 is depressed to inject the liquid diluent from the syringe 60 into the second vial 50 containing the powdered drug. After mixing the solution, the reconstituted drug is withdrawn from the second vial 50 into the syringe

60. The syringe 60 is then detached from the transfer device, and can be used to deliver the reconstituted drug.

Brenneman therefore teaches a transfer device having a syringe 60 that is directly connected to a third fluid passageway 25 (i.e., without a housing for receiving at least a part of the syringe). In contrast, Claim 1 as amended requires that the system includes a socket for receiving at least a part of the first container comprising fluid displacement means for moving fluid into and out of the container (e.g., a syringe). Additionally, Brenneman teaches a two-step process for delivering the reconstituted drug. Firstly, the syringe 60 is detached from the transfer device. Secondly, the detached syringe 60 is then used to deliver the reconstituted drug. The transfer device taught by Brenneman could not be used to directly deliver the reconstituted pharmaceutical. In contrast, Claim 1 as amended requires a tubulation connected to the system for delivery of the multi-component pharmaceutical directly therefrom. Accordingly, applicant respectfully submits that Brenneman does not teach the two features noted above, nor is there any suggestion or motivation to modify Brenneman to arrive at same.

Haber et al. (US Patent No. 5,562,569) teaches a mixing and delivery device that includes two separate valves that can be independently operated to alternatively connect a syringe and a vial, and the syringe and an IV bag. In contrast, Claim 1 as amended requires a body comprising a diverter valve and first, second and third vessels extending from the open ends of the diverter valve which valve is operative to alternatively connect the first and second vessels or the first and third vessels.

Furthermore, the Examiner has cited Haber et al. as teaching connection of both a vial and an IV bag to a mixing and delivery device. However, a vial and an IV bag are both types of containers adapted to hold a fluid whereas a tubulation is a conduit that permits the passage of a fluid from one position to another. Accordingly, neither a vial nor an IV bag is interchangeable with a tubulation since they are used for very different purposes. Accordingly, applicant respectfully submits that Haber et al. does not teach connecting a tubulation to a mixing and delivery device for delivery of a

multi-component pharmaceutical, nor is there any suggestion or motivation to modify Haber et al. to arrive at same.

Morell (US Patent No. 5,389,070) teaches an apparatus that includes a first syringe 11 with a needle 30 for injecting medications, a three way stopcock 35 positioned within the first syringe 11, and a second reservoir syringe 40. The stopcock 35 can be positioned to interconnect the first syringe 11 with the needle 30 to provide a first flow path to permit injection of a medication to a patient. Alternatively, the stopcock 35 can be positioned to interconnect the first syringe 11 with the second reservoir syringe 40 to provide a second flow path to permit the first syringe 11 to be refilled with medication from the second reservoir syringe 40 for subsequent injection into the patient. There is no teaching to use the device to deliver a multi-component pharmaceutical. Rather, the focus of Morell's disclosure is that the first syringe 11 can be refilled without removal of the needle from the patient. Additionally, the tubulation in Morell's device is part of the second reservoir syringe 40, and is therefore not for delivery of a multi-component pharmaceutical as specified in Claim 1 as amended. In contrast, Claim 1 as amended is directed to a system having a diverter valve that is operative to alternatively connect a first container comprising fluid displacement means and a second container, and the first container and a tubulation for delivery of a multi-component pharmaceutical. It is submitted that there is no teaching or suggestion in Morell that would lead a skilled person in the art to substitute or modify the device or combine it with Brenneman's device in a way that would result in the system as claimed in Claim 1 as amended.

Lynn et al. (US Patent No. 5,549,569) teaches a blood sampling system 200 that includes a valve 214 connected to a second conduit 212, a syringe 5', and a third conduit 218. A high-pressure fluid source is positioned within the third conduit 218. In operation, the system 200 is filled with resident fluid (such as saline) and connected to catheter 208 that has been inserted into the blood vessel 209 of a patient. During this time, the valve 214 is closed to the syringe 5' and opened to provide fluid communication between the high-pressure source and the blood vessel 209. When a blood sample is desired, the valve 214 is positioned so that fluid communication is opened between the syringe 5' and the blood vessel 209 and

closed to the high-pressure source (see col. 13, lines 11-54 and Figures 8-9). Lynn et al.'s device is not directed to the delivery of a multi-component pharmaceutical. The device is one that simply allows blood to be drawn from a patient as required, without removal of the catheter. The device also permits flushing of the cannula. The device can be used to administer a drug, but similarly, the device is designed to permit flushing with a saline solution after injection of a drug (see col. 14, line 58 to col. 15, line 29). There is no teaching that the valve should operate to fluidly connect the syringe and the high-pressure source. Nor is there any reason why a skilled person in the art would modify Lynn et al.'s device to connect the syringe and the high-pressure source. In contrast, Claim 1 as amended is directed to a system having a diverter valve that is operative to alternatively connect a first container comprising fluid displacement means and a second container, and the first container and a tubulation for delivery of a multi-component pharmaceutical. It is submitted that there is no reason why a skilled person in the art would be motivated to adapt Lynn et al.'s device to arrive at the invention as claimed in Claim 1 as amended in the instant application.

Nowakowski (US Patent No. 6,159,232) teaches a wound closure apparatus that utilizes blood by activating the clotting cascade of the blood outside the body within a substantially closed container and subsequently introducing the blood to the wound site to complete clotting. The device includes a three way valve connector 7 connected to a syringe 1, a tubing section 11 (e.g., a vent), and a container that consists of a cylinder 9 and two luer lock cylinder cap fittings 8, 10 and is filled with an anti-coagulant binding material 14 and porous material 13, 15. A three-way connector 6 connects a pulsitile indicator 16, the container, and a catheter 29. The catheter 29 has a port 21 that is inserted into the inside of an artery 36. In operation, the valve 7 is initially positioned to provide fluid communication between the container and the syringe 1. The syringe plunger is withdrawn to cause blood to flow up the catheter 29 and through materials in the container. As this occurs, trapped air within the syringe 1 may be exhausted through the vent 11 by switching the position of the three-way valve 7 to provide fluid communication between the syringe 1 and the vent 11 and advancing the plunger. Once substantially exhausted of air, the three-way valve 7 is returned back to the position that permits blood to enter the

syringe 1 upon withdrawal of the plunger. As blood flows through the materials in the container towards the syringe 1, the clotting cascade is activated. Next, the catheter's 29 distal port 21 is removed from the artery. The syringe 1 plunger is advanced thereby driving clot-activated blood out of the distal port 21 and depositing it around the wound where clotting continues. Importantly, Nowakowski's device includes a tubing section 11 that permits venting of excess air from the syringe 1. The tubing 11 does not in any way related to the delivery of a reconstituted pharmaceutical. Moreover, Nowakowski's device does not relate to delivery of a multi-component pharmaceutical. In fact, a skilled person would not modify Nowakowski's device in the way suggested by the Examiner because delivery of the pharmaceutical is effected through catheter 29 which is connected to container 9, 8, 10 and not to the valve 7. In contrast, Claim 1 as amended is directed to a system having a diverter valve that is operative to alternatively connect a first container comprising fluid displacement means and a second container, and the first container and a tubulation for delivery of a multi-component pharmaceutical. There is no teaching suggestion or reason why a skilled person in the art would modify Nowakowski's device to combine it with the teaching of Brenneman and arrive at the invention as claimed in Claim 1 as amended.

Overall, as acknowledged by the Examiner, none of the references cited by the Examiner disclose the exact combination of elements as claimed in amended Claim 1. The applicant respectfully submits that there is no teaching in any of the references as to why or how a person skilled in the art would re-combine the references to obtain the system of the instant invention. Without the existence of such a teaching or suggestion, it is submitted that there would have been no motivation or reason for a skilled person to combine the cited references to arrive at the claimed invention. For example, if one were to follow the teachings of the prior art, a person skilled in the art would modify the transfer device of, for example, Brenneman by replacing one of the vials with an IV bag of Haber et al.

Claims 2-6, 8-9 and 12 depend from amended Claim 1. Applicant respectfully submits that Claims 2-6, 8-9 and 12 are not rendered obvious by the references cited for at least the reasons given for amended Claim 1.

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's undersigned lawyer at the telephone number listed below.

Respectfully submitted,

BERESKIN & PARR

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Attachments

Replacement Sheet